K093773

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AMSINO
Advancing Healthcare Worldwide®

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SPECIAL 510k PREMARKET NOTIFICATION

February 11, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (WO66-0609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Reference:

Dear Madam/Sir:

AMSINO International, Inc. hereby submits this **Special 510(k):** for *AMSURE ® I.V. Administration Set,* a modification of our previously cleared *AMSURE® I.V. ADMINISTRATION SET (k973107).* We consider our intent to market this device as confidential commercial information and requests that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at *(909) 626-5888, extension 127 or at jesus_farinas@amsino.com*

Sincerely,

Jesus T. Farinas
Manager, Quality Assurance and Regulatory Affairs

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (WO66-0609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 11, 2010
Re SPECIAL 510(k) Submission
AMSINO® I.V. ADMINISTRATION SET

Attention Document Mail Clerk

AMSINO INTERNATIONAL, INC. is requesting marketing clearance for the *AMSINO® I.V. ADMINISTRATION SET*, a modification of a previously cleared device: *AMSURE® I.V. ADMINISTRATION SET*, (k973107) The premarket notification information required by 21 CFR 807.87 is as follows:

a. Classification Name: *Set, Administration, Intravascular*
b. Common/Usual Name I.V. Administration Set

c. FDA Establishment Registration Number 2085175

d. Owner/Operator Identification Number 9008588

e. Classification: Class II device
Classification Number: FPA
880. 5440

f. Statement of Intended Use:

The *AMSINO® I.V. ADMINISTRATION SET* is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

g. Label/Labeling/Advertisements: A sample of the *AMSINO® I.V. ADMINISTRATION SET AND* package labeling are enclosed (Appendices 2 & 3).

h. Substantial Equivalence: The *AMSINO® I.V. ADMINISTRATION SET* is made from the same material, manufactured and processed in the same manner and has the same intended use as the predicate device, the *AMSINO® I.V. ADMINISTRATION SET (k973107)*

In addition, the *AMSINO® I.V. ADMINISTRATION SET* is substantially equivalent to currently legally marketed predicate devices in material, technology and intended use as the *AMSINO® I.V. ADMINISTRATION SET (k971037).*

Statement of Technological Characteristic of the Device:
The *AMSINO® I.V. ADMINISTRATION SET* meets the Bench performance testing requirement according to ISO 8536-4 when appropriate and/or AMSINO's testing and acceptance criteria: (see Appendix 4)

Closure Piercing Device (Spike) Features
Air Inlet Device Characteristics
Connector Performance criteria: i.e. to prevent leakage
Drip Chamber and Drip Tube Performance
Flow Regulator Performance
Flow characteristics
Tensile Strength of Connectors
Self-sealing injection site challenge test
The number of injection port access to failure for needleless port with valves, diaphragms or membranes.

Biocompatibility and Hemocompatibility: Biocompatibility assessment of the *AMSINO® I.V. ADMINISTRATION SET* has been conducted based on the guidelines established by various governmental and standard setting organizations such as ISO 10993-1- Biological Evaluation of Medical Devices. Based upon the results of this prolonged duration, indirect blood path containing device assessment; (Cytoxicity, Sensitization, Irritation, Systemic Cytoxicity and Hemocompatibility testing) the materials used to fabricate the *AMSINO® I.V. ADMINISTRATION SET,* have been shown to be biocompatible, hemocompatible, and appropriate for its intended use. (See Appendix 6)

Sterility: *AMSINO® I.V. ADMINISTRATION SET* is sterilized by Ethylene Oxide as validated per ISO 11135-1:2007-Sterilization of Healthcare products – Ethylene Oxide - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices. (See Appendix 7)

Pyrogenicity: *AMSINO® I.V. ADMINISTRATION SET* is tested for pyrogenicity (see Bench Test table). (See Appendix 4)

Microbial Ingress Challenge Test: Amsino's testing of potential microbial ingress demonstrates a 4-log reduction of micro-organisms against gram negative and gram positive organisms using the proper aseptic technique. (See Appendix 5)

The *AMSINO® I.V. ADMINISTRATION* is substantially equivalent to the predicate devices in technology, materials used and intended use as the *AMSINO® I.V. ADMINISTRATION SET (k973107).*

Sincerely Yours,

Jesus Farinas
Manager, Quality Assurance and Regulatory Affairs

SPECIAL 510k SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter and Contact Person:
AMSINO International, Inc
855 Towne Center Drive,
Pomona, CA 91767
Jesus T. Farinas
Manager, Quality Assurance and Regulatory Affairs
Telephone Number : (909) 626-5888, ext 127
Email: jesus_farinas@amsino.com

Establishment Number: **2085175**
Name of the Device:
Classification Name: Set, Administration, Intravascular
Proprietary Name: *AMSINO® I.V. ADMINISTRATION SET*

510k number: **k093773**
Regulation Number: **880.5440**
Class: **II**
Classification Product Code: **FPA**

Predicate Devices:
AMSINO® I.V ADMINISTRATION SET (k973107)

Intended use of the Device:
The *AMSINO® I.V. ADMINISTRATION SET* is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

Device Description:
The *AMSINO® I.V. ADMINISTRATION SET* is a single use, latex-free, Non-DEHP, gravity feed, sterile device sterilized with Ethylene Oxide Gas. It is used to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein. It is comprised of various components such as: bag, spike, drip chamber (vented and non-vented), Y-site, burette, tubing, flow controller, drip selector, clamp, check valve, latex-free injection site, needleless injection site, flashbulb, filter, manifold, stopcock, flash bulb, luer connectors and bag hanger.

This submission is an extension of the original approval (k973107) and covers the following AMSINO Product Line:

AMSINO® STANDARD I.V. ADMINISTRATION SET
AMSafe® I.V. ADMINISTRATION SET *(identical to the Amsino Standard I.V. Administration set, except it is marketed for Emergency Medical Services group/personnel)*

AMSafe3® I.V. ADMINISTRATION SET *(identical to AmSafe I.V. Administration Set, with the exception of the drip selector option.)*

AMSINO offers both standard and custom sets with tubing of various sizes and lengths with a choice of 10, 15, 20 and 60 drops per ml to meet customer requirements and specifications. Customers may request I.V. Administration sets with varying configuration containing any combination of the parts per the table:

Tubing	Bag Spike	Filter	Bag Hanger
Drip Chamber	Clamp	Rotating male luer lock	Y-site
Needleless injection site	Flow Controller	Male or Female luer lock	stopcock
Split Septum Injection Site	Drip Selector	Check Valve	manifold

Technological Characteristics Summary:

AMSINO® I.V. ADMINISTRATION SET is constructed of high grade extruded DEHP-free PVC. Component material list is herewith attached (see device drawings). The intended use, the basic design, function and the materials used to construct the IV Administration Set is identical to the predicate device and other devices currently legally marketed and are substantially equivalent. This premarket notification is an update of the performance and biocompatibility data of the currently approved predicate device – the Amsino I.V. Administration Set (k971037).

Performance Data

The *AMSINO® I.V. ADMINISTRATION SET* meets the **Bench performance testing** requirement according to ISO 8536-4 when appropriate and/or AMSINO's testing and acceptance criteria:

Closure Piercing Device (Spike) Features
Air Inlet Device Characteristics
Connector Performance criteria: i.e. to prevent leakage
Drip Chamber and Drip Tube Performance
Flow Regulator Performance
Flow characteristics
Tensile Strength of Connectors
Self-sealing injection site challenge test
The number of injection port access to failure for needleless port with valves, diaphragms or membranes.

Biocompatibility and Haemocompatibility: Biocompatibility assessment of the *AMSINO® I.V. ADMINISTRATION SET* has been conducted based on the guidelines established by various governmental and standard setting organizations such as ISO 10993-1- Biological Evaluation of Medical Devices. Based upon the results of this prolonged duration, indirect blood path containing device assessment, (Cytoxicity, Sensitization, Irritation, Systemic Cytoxicity and Hemocompatibility testing) the materials used to fabricate the *AMSINO® I.V. ADMINISTRATION SET,* have been shown to be biocompatible, hemocompatible, and appropriate for its intended use. The test results indicate neither sensitivity, nor toxicity and slight irritation is associated with the AMSINO I.V. Administration Set. Test data demonstrate that the AMSINO I.V. Administration Set is haemocompatible.

Sterility: *AMSINO® I.V. ADMINISTRATION SET* is sterilized by Ethylene Oxide as validated per ISO 11135-1:2007-Sterilization of Healthcare products – Ethylene Oxide - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.

Pyrogenicity: *AMSINO® I.V. ADMINISTRATION SET* is tested for pyrogenicity (see Bench Test table).

Microbial Ingress Testing: Amsino's testing of potential microbial ingress demonstrates a 4-log reduction of micro-organisms against gram negative and gram positive organisms using the proper aseptic technique.

The *AMSINO® I.V. ADMINISTRATION SET* is substantially equivalent to the predicate devices in technology, materials used and intended use as the *AMSINO® I.V. ADMINISTRATION SET (k973107).*

Prepared by:

Jesus Farinas, QA/RA Manager

11 FEB 2010

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 10 2010

Mr. Jesus T. Farinas
Manager, Quality Assurance and Regulatory Affairs
Amsino International, Incorporated
855 Towne Center Drive
Pomona, California 91767

Re: K093773
Trade/Device Name: AMSINO® I.V. ADMINISTRATION SET
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 11, 2010
Received: February 12, 2010

Dear Mr. Farinas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **k093773**

Device Name: *AMSINO® I.V. ADMINISTRATION SET*
Indications For Use:

The *AMSINO® I.V. ADMINISTRATION SET* is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

Prescription Use__X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093773